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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,093	10/19/2001	S. Rao Cherukuri	24222-X3	6757
7590 S RAO CHERUKURI 6900 English Muffin Way Unit A Frederick, MD 21703			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/19/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.		Applicant(s)	
	09/982,093		CHERUKURI, S. RAO	
	Examiner		Art Unit	
	Blessing M. Fubara		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1618

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and request for reconsideration, all filed 9/21/06. Claims 1 and 3-24 are pending. Claims 8-24 are withdrawn from consideration. Claims 1 and 3-7 are examined.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carmelm et al. (US 4,053,632).

Amended claim 1 is a product that consists of a), b), c) and d). The d) part of claim one is a binder and binder is generic to acacia, alginic acid, carbomer, carbopol, carboxymethylcellulose sodium, dextrin, ethyl cellulose, gelatin, guar gum, hydrogenated vegetable oil, hydroxyethyl cellulose, hydroxypropyl cellulose, KLUCEL, hydroxypropyl methyl cellulose, METHOCEL, liquid glucose, magnesium aluminum silicate, maltodextrin, methylcellulose, polymethacrylate, povidone, KOLLIDON, PLASDONE, pregelatinized starch, sodium alginate, starch crystalline cellulose, cellulose derivative, acacia, corn starch, gelatin, tragacanth and gum (see for example, paragraphs [0197], [0479], [0264] and [0062] of US

Art Unit: 1618

20060272050 A1, US 20060270695 A1, US 20010056365 A1 and US 20010055613 A1 respectively for what binders are in tablet formulations).

Carmelm discloses synthesis of neuroleptic agents of the spiro amine type compound (abstract, title) and the compounding of the neuroleptic compounds into tablet formulations having diameters of 6 and 10 mm (Examples 21 and 22). Antipsychotics are known as neuroleptics (column 1, lines 20 and 21 of US 6,294,530; column 1, lines 57 and 58). Carmelm synthesizes neuroleptics (Examples 15) and combines it with lactose, starch and magnesium stearate (Examples 21), which is compressed to tablets with a diameter of 6 mm (Example 21) and 10 mm (example 22). Lactose meets claim 1 b); starch meets claim 1 c) and magnesium stearate meets claim 1 c). The neuroleptic, which is anti-psychotropic and which can also be insomnia therapeutic (abstract of "Rebound insomnia in neuroleptic drug withdrawal neurophysiologic characteristic," Pharmacopsychiatry, 1987 May; 20 (3)) and antidepressant (column 5, line 2 of US 5,919,780; column 4, lines 56 and 57 of US 5,866,585), meets claim 3-6. The diameter of 6 mm meets the size requirement of claim 1. While Carmelm does not disclose any of the drugs listed in claim 7, it would be obvious to one of ordinary skill in the art to use one neuroleptic/antidepressant with the expectation of obtaining antipsychotic or antidepressant or neuroleptic activity. Specifically, the share number of the antidepressants listed in claim 7 indicates that any of the listed antidepressant is effective in the claimed dosage form. However, Carmelm discloses about 1% of the magnesium stearate lubricant while the claimed invention uses an amount of up to 5%. The recitation of an amount "of up to 5%" encompasses an amount of less than 5%. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use about 1% lubricant in tablet

Art Unit: 1618

Carmelm. One having ordinary skill in the art would have been motivated to use an amount of lubricant effective to provide desired tablet hardness, dissolution and disintegration. Thus in the absence of factual evidence, "up to 5%" lubricant is not patentable over a disclosure directing the use of the magnesium stearate lubricant at about 1%.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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